QUEEN'S UNIVERSITY BELFAST

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Development and Review of Research Plan / Study Protocol**		
SOP Reference Number:	QUB-RGEI-002	Version Number	FINAL v 1.0
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	Name and Position	**Signature**	**Date**
Author:	Research Governance, Ethics and Integrity Team	----------	----------
Reviewed and Approved by:	Chair, Research Governance, Ethics and Integrity Committee	----------	----------

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) describes the process for developing and reviewing a research study protocol – or the study plan.

For researchers undertaking a clinical study it contains the necessary information to assist researchers to write a protocol in accordance with the ICH Guidelines for Good Clinical Practice (ICH-GCP) standards for clinical trials. For those involved in other forms of research it provides key headings that may help when developing the research plan.

2. Introduction

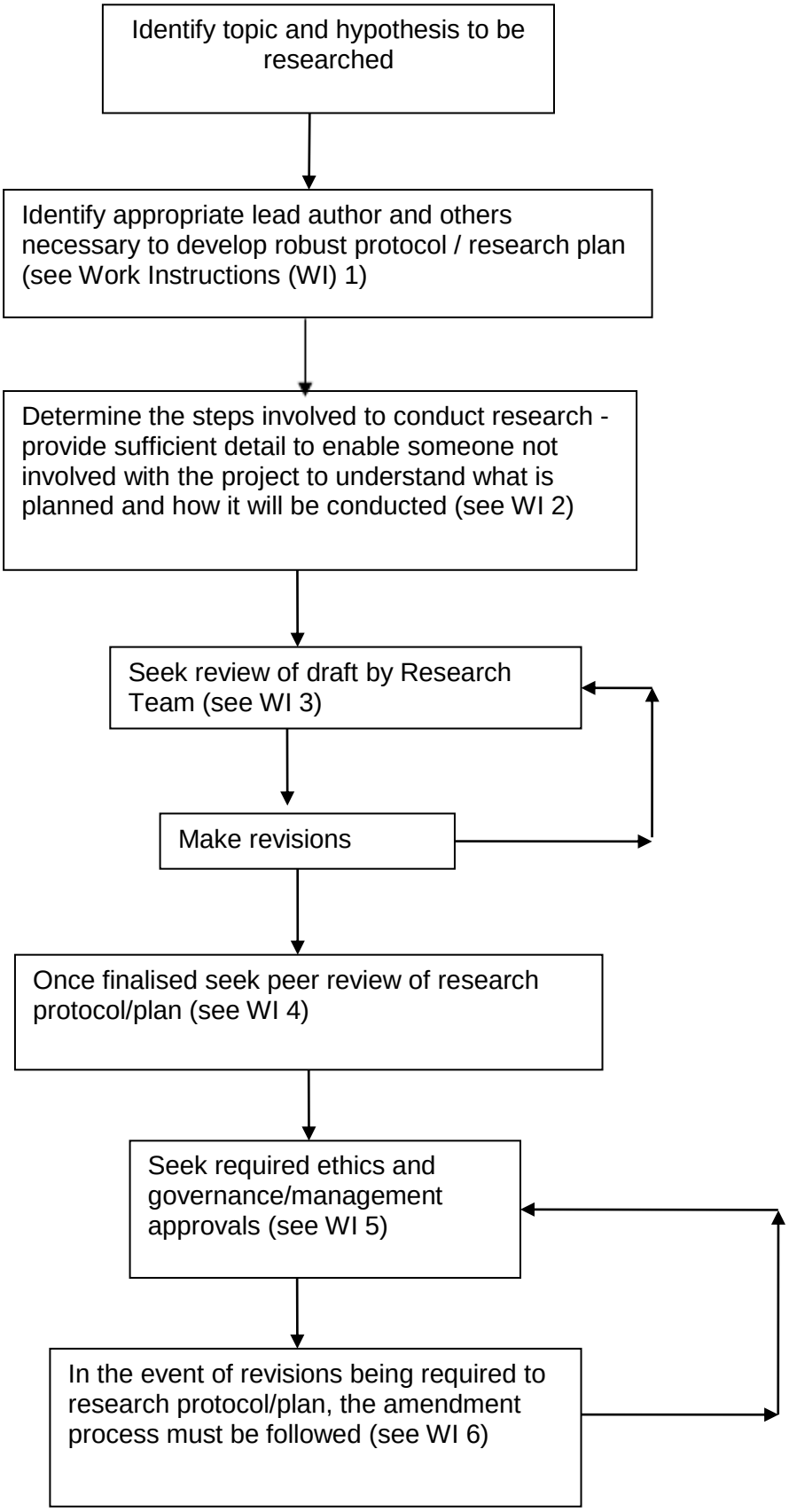
A research protocol is a document that details the plan for a proposed research study. The development of a new study is the responsibility of the lead academic and, if necessary, the relevant clinical team from the Health and Social Care (HSC) setting. When developing the research consideration should be given to Patient and Public Involvement (PPI) and opportunities to include PPI taken, where feasible. It is also important to involve the suitable expertise of biostatisticians, information technology/database experts, and relevant other experts as appropriate when drafting the protocol

The Chief Investigator may delegate the responsibility for writing the protocol and its associated documents to a designated qualified individual.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

4. Procedure


Identify topic and hypothesis to be researched
Identify appropriate lead author and others necessary to develop robust protocol / research plan (see Work Instructions (WI) 1)
Determine the steps involved to conduct research - provide sufficient detail to enable someone not involved with the project to understand what is planned and how it will be conducted (see WI 2)
Seek review of draft by Research Team (see WI 3)
Make revisions
Once finalised seek peer review of research protocol/plan (see WI 4)
Seek required ethics and governance/management approvals (see WI 5)
In the event of revisions being required to research protocol/plan, the amendment process must be followed (see WI 6)

5. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1).
http://www.ich.org/products/guidelines.html (last accessed 09 July 2021).
University College London, Standard Operating Procedure, Writing a Protocol to Good Clinical Practice (GCP).
HRA Template for Research Protocol: https://www.hra.nhs.uk/documents/324/qualitative-protocol-development-tool.docx

6. Work Instructions and Appendices

Work Instructions 1 - Authors of Research Protocol/Research Plan
Work Instructions 2 – Identification of Steps Involved in the Research
Work Instructions 3 – Review of Research Protocol/Plan
Work Instructions 4 – Peer Review
Work Instructions 5 – Governance and Ethics approvals
Work Instructions 6 – Amendments to Research Protocol/Plan

Appendix 1: Protocol Template

Work Instructions 1 – Authors of Research Protocol/Research Plan

1. The Chief Investigator should identify who is best qualified to write the research protocol/research plan, be it clinical or non-clinical.
2. Patient Public Involvement in the development of the research may be a requirement by Funders and will provide a different perspective on the planned research.
3. Input should be sought from others with relevant skills and knowledge. This may include Statisticians to ensure the research is correctly powered, information technology/database experts, information compliance professionals, or relevant other discipline experts.

Work Instructions 2 – Identification of Steps Involved in the Research

1. Background and rationale - The research protocol/research plan should be developed on the basis of the literature relevant to the area to be studied. The background literature should also include the methods identified.
2. Objectives – A detailed description of the objectives and purpose of the study which may include both primary objectives and secondary objectives.
3. Study Design – This should be a description of the design/type of study to be carried out that details each stage of the process. In particular:
    a. how participants are to be recruited to the study;
    b. what inclusion or exclusion criteria are to be used;
    c. the number of participants required;
    d. how and when initial consent shall be sought and the process for ongoing consent, if relevant;
    e. what procedures/interventions/interactions there shall be with research participants;
    f. how many times procedures/interventions/interactions will take place;
    g. where these shall take place;
    h. over what time period this will occur;
    i. what mechanism is being used to capture the research data being collected;
    j. how participants can withdraw from the research and what will happen to any data or human tissue collected up to that point;
    k. what is considered as the study being completed e.g. last participant recruited, last participant having completed the study, the study data having been analysed or reported on.

Work Instructions 3 – Review of Research Protocol/Plan

1. Once drafted, the research protocol/plan should be circulated to those persons previously identified who are relevant experts to ensure the planned research is scientifically robust.
2. The research protocol/plan should be considered by those persons to ensure it meets with any applicable regulatory requirements and that it is ethically sound.
3. Comments raised should be dealt with and then the protocol/plan revised and re-circulated until all points are addressed satisfactorily.
4. Once approved amongst the research group the document should then be dated and a version number allocated.

Work Instructions 4 – Peer Review

1. The research protocol/plan should be peer reviewed in accordance with the University's Regulations for Research Involving Human Participants.
2. If required, further changes should be made following peer review and the version number updated, along with date finalised.

Work Instructions 5 – Governance and Ethics approvals

Research involving human participants, their tissues or data, research involving animals, or research that may have significant environmental issues must be considered by an appropriate ethics committee, as outlined in the Policy on the Ethical Approval of Research.

1. The CI must liaise with the
    a. University's Research Governance Team if the research involves the health and social care sector;
    b. Chair of the Animal Welfare Ethical Review Body if the research is governed by the Animal Scientific Procedures Act (1986);
    c. The University Research Ethics Officer if the researcher is based within the Faculty of MHLS or EPS or involves animal welfare studies not governed by ASPA;
    d. The relevant School REC Chair in AHSS;
    e. University's Information Compliance Team where research involves personal data; to ensure that the appropriate procedures are followed.
2. The CI must ensure necessary approvals are sought and in place prior to research commencing, this may also necessitate local management permissions as well as ethical approvals.
3. The CI must retain a copy of the appropriate regulatory, ethical, management approvals for their study master file and ensure they are accessible in the event of an audit.
4. The CI must ensure that source documents that contain source data are retained. Source data is the original records of findings, observations, lab books or other activities used in the research.

Work Instructions 6 – Amendments to Research Protocol/Plan

1. Any changes to the protocol should be notified to the sponsor and the appropriate amendment process followed.
2. The Funding body (if relevant) must also be kept informed of any proposed changes.
3. A record must be retained of amended research documentation and subsequent approvals.
4. Deviations from approved protocols with prior approval should only occur in order to project research participants against any immediate hazard to their health and safety. In the event that a deviation does occur this should be discussed with the appropriate persons named in Working Instruction 5, point 1 above.
5. Ensure SOP QUB-RGEI-010 Amendments to Study Documentation is followed.

Study Title: insert full title

Internal Reference No: This should be assigned by the investigator/department

Ethics Ref: Insert

IRAS ID: Insert

Date and Version No: Insert

Chief Investigator:	Insert name and contact details
Investigators:	Insert names of key collaborators
Sponsor:	
Funder (if applicable):	Insert details of organisation providing funding

Include other relevant information as necessary e.g. name of Contract Research Organisation, Medical/Safety Monitor.

TABLE OF CONTENTS

- **AMENDMENT HISTORY**

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

- **SYNOPSIS**

It may be useful to include a synopsis of the study for quick reference. Delete or alter as appropriate/required.

Study Title	
Internal ref. no.	
Study Design	
Study Participants	
Planned Sample Size	
Follow-up duration	
Planned Study Period	
Primary Objective	
Secondary Objectives	
Primary Endpoint	
Secondary Endpoints	
Intervention (s)	

- **BACKGROUND AND RATIONALE**

Outline the scientific justification for the research. Give an outline of the background to the study, with references to literature and other relevant research.

Give an outline of the main research questions. Give a brief outline of the intervention (if applicable) and summary of findings from previous studies (if relevant) that potentially have clinical significance.

Provide summary of the known and potential risks and benefits of any of the study procedures (where applicable)

Describe the population to be studied.

- **OBJECTIVES**

There is usually only one primary objective, the rest are secondary objectives.

The wording of the objectives should be clear, unambiguous and as specific as possible.

- **4.1 Primary Objective**

Insert primary objective

- **4.2 Secondary Objectives**

Insert secondary objectives

- **STUDY DESIGN**

5.1 Summary of Study Design

Describe the overall study design e.g., double-blind, sham-controlled, parallel design, open labelled, observational.

Give the expected duration of participant participation, number of visits, and a description of the sequence and duration of all study periods.

- **5.2 Primary and Secondary Endpoints/Outcome Measures**

Describe the end-points/outcome measures and how/when they will be measured during the study.

Endpoints/outcome measures should reflect the objectives. It is important that only one primary endpoint/outcome measure is selected as it will be used to decide the overall results or 'success' of the study. The primary endpoint/outcome measure should be measurable, clinically relevant to participants and widely accepted by the scientific and medical community.

5.3 Study Participants

- **5.3.1 Overall Description of Study Participants**

Give an overall description of the study participants.

Example:

Participants with <<medical condition>> of *xyz* severity and <<*other symptoms/disease specific criteria*> or healthy adults aged <<insert age>>.

- **5.3.2 Inclusion Criteria**

Example criteria (amend as appropriate):

Participant is willing and able to give informed consent for participation in the study.
Male or Female, aged 18 years or above.
Diagnosed with required disease/severity/symptoms, any specific assessment criteria for these)
Additional criteria as required

5.3.3 Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

Specify any diseases/disorders/ conditions that would preclude entry into the study
Additional criteria as required

1.4 Study Procedures

Describe all study procedures and assessments in detail. Add visit numbers as appropriate. Add schedule of procedures as an appendix if appropriate.

5.4.1 Informed Consent

It should be specified who will take informed consent and how and when it will be taken. Informed consent should be obtained prior to any study related procedures being undertaken.

5.4.2 Study Assessments

List and describe each assessment specifying time points. Include screening and eligibility assessment, baseline and subsequent assessments.

- **5.5 Definition of End of Study**

The definition of end of study must be provided. In most cases the end of study will be the date of the last visit of the last participant. Any exceptions should be justified.

Example:

The end of study is the date of the last <<visit/ telephone follow up/ home visit>>of the last participant.

- **INTERVENTIONS**

Describe interventions (if applicable) including the name(s) of procedure/device, intervention schedule(s), treatment period(s), if applicable

- **SAFETY REPORTING (IF APPLICABLE)**

- **7.1 Definition of Serious Adverse Events**

Example:

A serious adverse event is any untoward medical occurrence that:

- Results in death,

- Is life-threatening,

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

- Requires inpatient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Other important medical events*

*Other events that may not result in death, are not life threatening, or do not require hospitalisation, may be considered a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

- **7.2 Reporting Procedures for Serious Adverse Events**

- A serious adverse event (SAE) occurring to participant should be reported to the REC that gave a favourable opinion of the study where in the opinion of the Chief Investigator the event was: 'related' – that is, it resulted from administration of any of the research procedures; and 'unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence. Reports of related and unexpected SAEs should be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES report of serious adverse event form (see NRES website**).**

- **STATISITICS**

- **8.1 The Number of Participants**

State the approximate number of participants required with justification.

- **8.2 Analysis of Endpoints**

Describe analysis of primary and secondary endpoints.

- **ETHICS**

Describe ethical considerations relating to the study. Include general and study specific ethical considerations.

- **9.1 Participant Confidentiality**

Example:
The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by initials and a participants ID number on the CRF and any electronic database. All documents will be stored securely and only accessible by study staff and authorised personnel. The

study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so.

9.2 Other Ethical Considerations

Include any other ethical considerations specific to the study e.g. involvement of vulnerable participants, participants who are unable to consent for themselves.

- **DATA HANDLING AND RECORD KEEPING**

Describe method of data entry/management

Example:
All study data will be entered on a <<quote software and validation procedure>>. The participants will be identified by a study specific participants number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

- **FINANCING AND INSURANCE**

Describe financing and insurance arrangements.

- **REFERENCES**

Insert references used in text.